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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202

ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of	mailing	g (day/	mont	th/y	ear)
	Anril				

International application No.

PCT/JP00/05367

International filing date (day/month/year)

10 August 2000 (10.08.00)

Applicant's or agent's file reference

FP00-0174-00

Priority date (day/month/year)

10 August 1999 (10.08.99)

Applicant

HIRASHIMA, Nobuchika et al

ı	1.	The designated Office is hereby notified of its election made:
		X in the demand filed with the International Preliminary Examining Authority on:
		09 February 2001 (09.02.01)
		in a notice effecting later election filed with the International Bureau on:
	2.	The election X was
		was not
		made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).
		·
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland **Authorized officer**

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Translation INTER

PATENT COOPERATION TREAT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP00-0174-00	FOR FURTHER ACT		ionofTransmittalofInternation Report (Form PCT/IPEA/4		
International application No.	International filing date	(day/month/year)	Priority date (day/month/y	vear)	
PCT/JP00/05367	10 August 2000	0 (10.08.00)	10 August 1999 ((10.08.99)	
International Patent Classification (IPC) or national classification and IPC A61K 9/70, 45/00, A61P 29/00					
Applicant HISA	Applicant HISAMITSU PHARMACEUTICAL CO., INC.				
 This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. This REPORT consists of a total of5 sheets, including this cover sheet. This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). 					
These annexes consist of a tot	tal of 9 sho	eets.	TECHNOLOGY CENTER IT	, H	
3. This report contains indications relat	ing to the following items	s:	NOTO	20	
Basis of the report		25			
3. This report contains indications relating to the following items:			20 1		
	of opinion with regard to n	novelty, inventive ste	另 p and industrial applicab斑		
IV Lack of unity of inve			3700		
V Reasoned statement citations and explana	under Article 35(2) with rations supporting such sta	regard to novelty, inv tement	entive step or industrial app	olicability;	
VI Certain documents c	ited			·	
VII Certain defects in the	e international application	ı			
VIII Certain observations	on the international appli	ication		_	
Date of submission of the demand	Г	Date of completion of	this report		
09 February 2001 (09.0	2.01)	30 N	May 2001 (30.05.2001)		
Name and mailing address of the IPEA/JP	A	authorized officer			
Facsimile No.		Telephone No.			

International application No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT/JP00/05367

I.	Basis	of the re	eport	
1.	With	regard to	o the elements of the international application:*	
		the inte	rmational application as originally filed	
	\boxtimes	the des	cription:	
		pages	1,3,4,7-9,12-22	, as originally filed
		pages	2,2/1,5,6,6/1,10,11	, filed with the demand
		pages	, filed with the letter of	
	\square	the clai	ms:	
		pages		, as originally filed
		pages		tement under Article 19
		pages	l l	
		pages	, filed with the letter of	
	\square	مام مامد		
	\triangle	the drav		as originally filed
		pages pages	1-7	
		pages	, filed with the letter of	
	_	-		
	L !	he seque	nce listing part of the description:	
		pages		
		pages		
		pages	, filed with the letter of	
2.	the in	iternatior	o the language, all the elements marked above were available or furnished to this Authority in the language, all the elements marked above were available or furnished, unless otherwise indicated under this item. Its were available or furnished to this Authority in the following language	n the language in which
	\square	the lang	guage of a translation furnished for the purposes of international search (under Rule 23.1(b)).	
		the lang	guage of publication of the international application (under Rule 48.3(b)).	A
	Ш	the langer or 55.3	guage of a translation furnished for the purposes of international search (under Rule 23.1(b)). guage of publication of the international application (under Rule 48.3(b)). guage of the translation furnished for the purposes of international preliminary examination). to any nucleotide and/or amino acid sequence disclosed in the international application was carried out on the basis of the sequence listing: ed in the international application in written form. gether with the international application in computer readable form. ed subsequently to this Authority in written form.	(under Rule 55.2 and/
3.	With prelin	regard ninary ex	to any nucleotide and/or amino acid sequence disclosed in the international applica camination was carried out on the basis of the sequence listing:	tion the Sternational
		contain	ed in the international application in written form.	ă » jii
		filed to	gether with the international application in computer readable form.	CE CE
	Ш	furnish	ed subsequently to this Authority in written form.	祖 赏 四
	Ш	furnish	ed subsequently to this Authority in computer readable form.	
			atement that the subsequently furnished written sequence listing does not go beyond tional application as filed has been furnished.	the declosure in the
			atement that the information recorded in computer readable form is identical to the writte rnished.	n sequence listing has
4.		The am	endments have resulted in the cancellation of:	
			the description, pages	
		$\overline{}$	the claims, Nos.	
			the drawings, sheets/fig	
5.		This rep	ort has been established as if (some of) the amendments had not been made, since they have the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**	been considered to go
	in thi	cement s s report 0.17).	heets which have been furnished to the receiving Office in response to an invitation under Ar as "originally filed" and are not annexed to this report since they do not contain am	ticle 14 are referred to endments (Rule 70.16
			ent sheet containing such amendments must be referred to under item 1 and annexed to this rep	port.
		-		

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

national application No.
PCT/JP 00/05367

citations and explanations support			
Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO NO

2. Citations and explanations

The following documents are cited in the international search report.

- Document 1: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 187062/1980 (Laid-open No. 111822/1982)
- Document 2: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 34256/1979 (Laid-open No. 134822/1980)
- Document 3: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 135016/1979 (Laid-open No. 60730/1981)
- Document 4: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 192794/1984 (Laid-open No. 108257/1986)

Documents 1-3 disclose rolled patches for external use, which are rolled around the outer surrounding surface a core.

Document 4 discloses a tape-protecting case which can cover the side surfaces of adhesive tape by fitting

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over the two edges of the core around which the roll of adhesive tape is rolled, and also describes a constitution wherein the side surfaces of the slots in said case have protrusions. It also indicates that soiling of the side surfaces of the tape can be prevented by said protective tape case (page 4).

Documents 1-3 do not disclose the feature of fitting a side cover, and the feature of forming the side cover of a polyacrylonitrile resin and/or poly(ethylene terephthalate) resin and forming the core from a polyacrylonitrile resin, poly(ethylene terephthalate resin), high-density polyethylene resin or polypropylene resin, and these features constitute a difference between the inventions set forth in the claims and the inventions disclosed in Documents 1-3.

On investigating said points of difference, it is common knowledge in the art that when forming a roll by winding an adhesive strip around the outside of a core, etc., the side surfaces are prone to soiling and the shape is prone to deformation, and solving these problems is a known technical problem. Therefore, adoption of the constitution of the case disclosed in Document 4 for a rolled external patch preparation disclosed in Document 1-3 for the purpose of preventing the adherence of dirt to the side surfaces thereof is obvious to a person skilled in the art. The constitution is also such that a person skilled in the art would expect it to have the effect of preventing deformation of the patch.

Next, forming the side cover of a polyacrylonitrile resin and/or poly(ethylene terephthalate) resin and forming the core from a polyacrylonitrile resin, poly(ethylene terephthalate resin), high-density polyethylene resin or polypropylene resin will be

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discussed. The adoption of plastics when selecting materials for the core and the side cover does not entail any difficulty when properties such as strength and ease of working and production are taken into account; and polyacrylonitrile resins, poly(ethylene terephthalate) resins, high-density polyethylene resins and polypropylene resins are known plastic materials.

Therefore, conception of the constitution of the inventions set forth in the claims of the present international application is obvious for a person skilled in the art.

The description of the present international application also indicates that forming the core and side cover with said resins controls adsorption of the active ingredient during storage. However, the comparison example presented in the "Tests evaluating persistence of the pharmacological effects" are an example in which the material of the core is paper and an example in which there are no side covers, and given the fact that in the former case paper can generally be expected to have a higher capacity for adsorption than plastic, and in the latter case loss of the active ingredient from the side surface of a patch would be expected to be decreased by the presence of side covers, these effects are such as would be expected by a person skilled in the art.

特 許 協 力 条 約



電話番号 03-3581-1101 内線 6247

REC'D 1 5 JUN 2001

WIPO PCT

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国際予備審査報告

(法第12条、法施行規則第56条) [PCT36条及びPCT規則70]

出願人又は代理人 の書類記号 FPOO-O174-00		いては、国際予備審査報告の送付通知(様式PCT/ IPEA/416)を参照すること。			
国際出願番号 PCT/JP00/05367	国際出願日 (日.月.年) 10.08.00	優先日 (日.月.年) 10.08.99			
国際特許分類 (IPC) Int. Cl ⁷	A61K9/70, 45/00, A61F	29/00			
出願人 (氏名又は名称) 久光製薬株式会社					
2. この国際予備審査報告は、この表紀 x この国際予備審査報告には、降	は は は は は は は は は は は は は は は は は は は	ジからなる。 皆礎とされた及び/又はこの国際予備審			
IV 開の単一性の欠如	を含む。 上の利用可能性についての国際予備審査報で ・る新規性、進歩性又は産業上の利用可能性				
国際予備審査の請求書を受理した日 09.02.01	国際予備審査報告を作 30.0 特許庁審査官(権限の	5. 01			
日本国特許庁(IPEA/JP) 郵便番号100-8915 東京都手代田区標が開三工日4番	田村 聖子				

様式PCT/IPEA/409 (表紙) (1998年7月)





1.	国際予備審査	報告の基礎 報告の基礎		
1.	この国際予備? 応答するため(PCT規則70.	こ提出された差し替え用紙は、	基づいて作成さ 、この報告書に	れた。(法第6条(PCT14条)の規定に基づく命令において「出願時」とし、本報告書には添付しない。
	出願時の国際	祭出願書類		
[x 明細書 明細書 明細書	第 1, 3, 4, 7-9, 12-22 第 2, 2/1, 5, 6, 6/1, 10, 11 第	_ ページ、 _ ページ、 _ ページ、 _ ページ、	出願時に提出されたもの 国際予備審査の請求書と共に提出されたもの 付の書簡と共に提出されたもの
[3	i 請求の範囲 請求の範囲 請求の範囲 請求の範囲	第	項、 項、 項、 項、	出願時に提出されたもの PCT19条の規定に基づき補正されたもの 国際予備審査の請求書と共に提出されたもの 付の書簡と共に提出されたもの
[3	図面 図面 図面	第 <u>1-7</u> 第	ページ/ 図、 ページ/図、 ページ/図、	国際予備審査の請求書と共に提出されたもの
	明細書の配列	刑表の部分 第 刑表の部分 第 刑表の部分 第	ページ、 ページ、 ページ、	出願時に提出されたもの 国際予備審査の請求書と共に提出されたもの 付の書簡と共に提出されたもの
2.	上記の書類は、 国際調査 PCT規	頭の言語は、下記に示す場合を下記の言語であるのために提出されたPCT規則48.3(b)にいう国際公開の言審査のために提出されたPC	語である 即23.1(b)にい 言語	る。 う翻訳文の言語
3.	この国際出願に	は、ヌクレオチド又はアミノ酢	俊配列を含んで	おり、次の配列表に基づき国際予備審査報告を行った。
	□ この国際 □ この国際 □ 出願後に □ 出願後に ■ 出願後に ■ 書面によ	出願に含まれる書面による配 出願と共に提出されたフレキ 、この国際予備審査(または 、この国際予備審査(または 提出した書面による配列表が があった	列表 シブルディスク 調査)機関に提 調査)機関に提 出願時における	/による配列表
4.	補正により、T] 明細書] 請求の範囲] 図面	デ記の書類が削除された。 第 第 図面の第	 項	ジ/図
5.	れるので、そ	着審査報告は、補充欄に示した との補正がされなかったものと ける判断の際に考慮しなければ	として作成した。	が出願時における開示の範囲を越えてされたものと認めら 、(PCT規則70.2(c) この補正を含む差し替え用紙は上 告に添付する。)



ての法第12	条(PCT35条(2))に定める見解、それを裏付	けける
請求の範囲 請求の範囲	1-10	_有 _無
請求の範囲 請求の範囲	1-10	有_無
請求の範囲 請求の範囲	1-10	有.無
1111111111111111111111111111111111111	062号 822号)の願書に添付した明細書 56号 822号)の願書に添付した明細書 016号 30号)の願書に添付した明細書 794号 57号)の願書に添付した明細書 794号 57号)の願書に添付した明細書	
	請請請請	請求の範囲 請求の範囲 1-10 請求の範囲 1-10 請求の範囲 1-10 請求の範囲 1-10 「「「「「「「」」」」 「「「」」」 「「」」 「「」」 「「」」 「「」」 「」 「



補充欄(いずれかの欄の大きさが足りない場合に使用すること)

第 V 欄の続き

該相違点について検討する。粘着性を有する帯状物を芯の外周に巻回す等してロー ル状物とした場合には、その側面が汚れやすいことや形状が変形しやすいことは技術 止する目的で文献4に記載のケースの構成を採用することは当該技術分野の専門家に 自明の事項である。また、貼付剤の変形を防止するという効果は、このような構成か ら当該技術分野の専門家が予測しうる程度のものである。

次に、サイドカバーをポリアクリロニトリル樹脂、ポリエチレンテレフタレート樹 脂により形成し、巻芯をポリアクリロニトリル樹脂、ポリエチレンテレフタレート樹 脂、高密度ポリエチレン樹脂又はポリプロピレン樹脂により形成する点について述べ 巻芯とサイドカバーの材料の選択に際して、強度、加工・製造の容易性等を考慮 すれば、プラスチック材料を採用することに何ら困難はない。そして、プラスチック 材料として、ポリアクリロニトリル樹脂、ポリエチレンテレフタレート樹脂、高密度 ポリエチレン樹脂及びポリプロピレン樹脂は周知のものである。

したがって、本国際出願請求の範囲に記載の発明の構成を想起することは当該技術

分野の専門家に自明のものである。 また、本国際出願明細書には、該樹脂により巻芯とサイドカバーを形成することに 「薬効保持性 より保存中の薬物の吸着を抑制することができる旨記載されているが、「薬効保持性評価試験」において比較例として示されているのは、巻芯の材質が紙のもの、およ び、サイドカバーを有さないものであって、前者については、一般に紙がプラスチックよりも高い吸着能を有すると考えられること、また、後者については、サイドカバ 一が存在すれば貼付剤側面からの薬物の散逸が減少すると考えられることに鑑みれ これら比較例に比して薬効保持性が優れていたとしても、そのような効果は当該 技術分野の専門家が予測しうるものと認められる。



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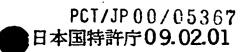
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変形等の不具合が生じることが無く、長期間に渡り薬効を保持することができ、 かつ貼付作業を容易に行うことができるロール状外用貼付剤を提供することを目 的とする。

本発明者らは、上記目的を達成するべく鋭意研究を重ねた結果、上記課題の要因としては、ロール状に巻回された貼付剤の両端面に粘着層断面が剥き出しになっておりこの部分から薬効成分が外部へ容易に逸散しまうことと、紙製の被覆材や巻芯が薬効成分を多量に吸着し易く保存中に薬効成分がこれらに移行して吸着されていることが影響していることを見出した。そして、これを解決するためには、薬効成分の吸着性及び透過性の低い材料で形成したカバーを用いてロール状に巻回された貼付剤の両端面を覆うことによって、薬効成分を粘着層内に保持することとロールの形状を保持することが可能となり、ひいては貼付作業も容易となることを見出した。

すなわち、本発明の貼付剤は、巻芯と、その外周面にロール状に巻回された外 用貼付剤と、巻芯の両端に取り付けられており、外用貼付剤を両側から覆う一対 のサイドカバーとを備え、各サイドカバーがポリアクリロニトリル樹脂又はポリ エチレンテレフタレート樹脂により形成されており、巻芯がポリエチレンテレフ タレート樹脂、ポリアクリロニトリル樹脂、高密度ポリエチレン樹脂及びポリプ ロピレン樹脂からなる群から選択される何れかにより形成されていることを特徴 とするものである。

上記のサイドカバーが外用貼付剤のロール状に巻回された貼付剤の両端面を覆うことによって、ロールの両端面への手垢等の汚れの付着が防止され、ロールの両端面からの薬効成分の逸散が抑制され、ロールの両端面の変形が防止される。また、このサイドカバーを備えることにより貼付剤のロールからの引出しやロールへの巻き取りがスムーズにしかも容易に行える。さらに、巻芯と各サイドカバーとが上記のプラスチック材料によりそれぞれ形成されていることで、薬効成分のこれらへの吸着が抑制されることとなる。



また、本発明のロール状外用貼付剤においては各サイドカバーが、ポリアクリロニトリル樹脂により形成されていることが好ましい。また、巻芯がポリエチレンテレフタレート樹脂またはポリアクリロニトリル樹脂により形成されているこ

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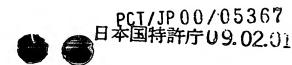




図3は、図2に示す帯状の貼付剤本体の平面図である。

図4A~Eはそれぞれ切り取り線に沿った方向から見た場合の外用貼付剤の拡大概略断面図である。

図5は、嵌合部の側面に突出部を設けたサイドカバーの斜視図である。

図6Aは図5に示すサイドカバーの正面図、図6Bは背面図、図6CはA-A線に沿う断面図、図6Dは図6Cに示すB-B線に沿う断面図である。

図7は、図5に示すサイドカバーを筒状の巻芯に嵌合させたロール状外用貼付 剤の斜視図である。

10 発明を実施するための最良の形態

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以下、図面を参照して本発明の好適な実施形態について更に詳しく説明する。 なお、図中、同一又は相当部分には同一符号を付することとする。

図1は本発明のロール状外用貼付剤の好適な実施形態の基本構成を断面図で示しており、図2は図1で使用される外用貼付剤本体の基本構成を拡大概略断面図で示している。

図1に示すとおり、本実施形態のロール状外用貼付剤10は、巻芯20と、この巻芯20の外周面に巻回された外用貼付剤30とからなる外用貼付剤30のロール40と、巻芯20の両端に取り付けられておりロール40の両端面をほぼ当接するように覆う一対のサイドカバー50から構成されている。

また、図2に示すとおり、外用貼付剤30は支持体32及びこの支持体32の表面のほぼ全面に積層された粘着層34とからなる本体、並びに粘着層34の表面のほぼ全面に使用時に剥がすために付着された被覆材36とから構成されている。

以下に各構成要素の詳細を説明する。巻芯20は筒状の形状を有している。この巻芯20の構成材料は、ポリエチレンテレフタレート樹脂、ポリアクリロニトリル樹脂、高密度ポリエチレン樹脂及びポリプロピレン樹脂からなる群から選択



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されるいずれか、又は、ポリエチレンテレフタレート樹脂、ポリアクリロニトリル樹脂、高密度ポリエチレン樹脂若しくはポリプロピレン樹脂のうちの少なくとも一種のプラスチック材料であればよいが、薬効成分の吸着性及び透過性の低い樹脂が好ましく、この観点からポリエチレンテレフタレート樹脂(PET)、ポリアクリロニトリル樹脂(PAN)等が好ましい。PET、PANを材料として選択することは、紙材のみならず、一般的な成型樹脂である高密度ポリエチレン樹脂(HDPE)、ポリプロピレン樹脂(PP)等を選択するよりも、巻芯20における薬効成分の損失を大幅に抑制する点で有効である。

巻芯20の大きさは特に限定されないが、巻芯20の長さはロール40の幅Wに等しいことが望ましい。このようにすることは、ロール40の両端面をサイドカバー50で当接し易くするので、ロール40の両端面からの薬効成分の逸散防止及びロール40の形状変形の防止の点で有効である。また、巻芯20は無色又は着色されていてもよい。

外用貼付剤30は帯状の形状を有している。この外用貼付剤30は、その帯の一端が巻芯30の外表面に固定され、支持体32の面を外側にして巻芯30に巻回されている。

外用貼付剤30を構成している支持体32は伸縮性を有する編布、織布又は不 織布からなる。この支持体32の構成材料としては、PET等の外用貼付剤30 に使用される薬効成分の吸着性及び透過性がともに極めて低い樹脂が好ましく使 用される。これにより、支持体32に起因する薬効成分の損失を使用前はもとよ り患部に貼付した後にも抑制することができる点で有効である。

また、支持体32は適度な柔軟性、および伸縮性を有していることが好ましい。 さらに、支持体32の厚みは0.01mm~5mmが好ましい。支持体1の厚み が0.01mm未満となるとハンドリングが悪くなり、シワが生じ易くなる傾向 にあり、他方、5mmを超えると柔軟性が低下し、貼付時に違和感が生じ、また 物理的な刺激が付与され易くなる傾向にあるからである。





粘着層34の構成材料は、特に限定されないが、薬効成分を含み常温で薬物を 皮膚表面に長時間固定し得る粘着力を有するものが好ましく、薬効成分を含む天



切れ目開きと不必要な破断が生じる傾向が大きくなり、上述の各上限値を越えると手切れ性に支障をきたし好ましくない。

上記のミシン目の切れ目60の好適な形成条件の下で作製された外用貼付剤30は、貼付部位の大きさに合わせて自由に貼付剤30のサイズが選択でき、容易に切り取ることができるとともに、手切れ性が良好で、切れ目開き、不必要な破断といった不具合が生じないこととなる。

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また、図4Bの切り取り線60の形成様式の変形例として図4C及び図4Dに示す支持体の一方あるいは両方に僅かな厚みを残して切り込みを入れる場合も考えられる。この「僅かな厚み」とは、使用時において貼付剤30を切り取る際に貼付剤30をわずかに屈曲させるか切り込みの両側から軽く引っ張るだけで容易に切り取れる程度の厚みを示す。貼付剤30は巻芯20に支持体32側を外側にして巻回されるので、特に図4C及び図4Dの様式にした場合に切り取り線の断面に起因する薬効成分の損失を有効に防止できる。このような様式は、特に揮発性の極めて高い薬効成分が含まれている場合に有効である。このように切り取り線として切り込み加工を施す場合には、切り込み線としては図4A、図4C~図4E等の様式が用いられる。なお、この場合「僅かな厚み」を好適な大きさに設定することによって、前述のミシン目の切れ目と同様の良好な手切れ性が実現でき、切れ目開き及び不必要な破断といった不具合を防止できることとなる。

サイドカバー50は図1に示すように中央部に凸部(嵌合部)が設けられた板体であり、この凸部(嵌合部)を筒状の巻芯20の内周面に当接するようにして巻芯20の両端にはめ込まれていることが好ましい。サイドカバー50は、巻芯20にはめ込まれると同時に、凸部(嵌合部)周辺の面をロール40の端面にほぼ当接させられる。これにより、ロール40の端面がサイドカバーで覆われるためロール40の両端面からの薬効成分の逸散を抑制することができるとともにロール40の形状変形と手垢等による汚れの付着を防止することができる。さらに、後述するように使用の際にもサイドカバーが備わっていること



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で外用貼付剤30の引出しや巻き取りが容易になる。

サイドカバー50の構成材料は、PAN又はPETから形成されていればよいが、薬効成分の吸着性及び透過性の低い樹脂が好ましく、この観点からPANが好ましい。PANを材料として選択することは、紙材のみならず、一般的な成型樹脂であるHDPE、PP等を選択するよりも、サイドカバー50における薬効成分の損失を大幅に抑制する点で有効である。

なお、サイドカバー50の外径Rは、ロール40のロール外径r(図示せず) 以上の大きさを有していることが望ましい。このようにすれば、ロール40の各 端面の全面を覆うことができ、薬効成分の逸散を抑制する点で有効である。また、 サイドカバー50は、ロール40の形状変形を有効に防止するために自身が容易 に変形しないように構成材料に合わせた適度な厚みを有していることが望ましい。

上記のロール状貼付剤10の使用方法は基本的に従来のロール状貼付剤と同様である。はじめに一方の手でロール状貼付剤10を持ち、ロール40から貼付剤30をもう一方の手の指でつまんで引き出す。この際に、サイドカバー50がロール40から引き出されてくる貼付剤30の帯の側端部を両側から支持してガイドの役目を果たし、ロール40から貼付剤30をスムーズに真っ直ぐ引き出すことができる。また、ロール状貼付剤10を持っている手の指は、サイドカバーがあるために粘着層34の剥き出しになったロール40の端面に触れることがないので、従来のようにこの部分が手垢等で汚れるような不具合はない。さらに、貼付剤30には被覆材が36が付着されているため貼付剤30には適度な剛性があり、引き出す時に多少の大きな引っ張り力が働いても支持体32が延びてシワができてしまう等の不具合もない。

次に引き出された貼付剤30の帯を患部の大きさに合わせて切断する。この際に、貼付剤30の支持体32及び被覆材34には、前述の手切れ性を良好に保ち、切れ目開きや不必要な破断といった不具合が生じないように切り込み加工が施してあるので、大きさを調節してカッターやはさみ等の刃物が無くとも容易に切断





請求の範囲

1. (補正後) 巻芯と、

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前記巻芯の外周面にロール状に巻回された外用貼付剤と、

前記巻芯の両端に取り付けられており、前記外用貼付剤の両端面を両側から覆う一対のサイドカバーとを備え、

前記各サイドカバーがポリアクリロニトリル樹脂又はポリエチレンテレフタレート樹脂により形成されており、

前記巻芯がポリエチレンテレフタレート樹脂、ポリアクリロニトリル樹脂、高密度ポリエチレン樹脂及びポリプロピレン樹脂からなる群から選択される何れかにより形成されているロール状外用貼付剤。

- 2. 前記各サイドカバーが、ポリアクリロニトリル樹脂により形成されており、 前記巻芯が、ポリエチレンテレフタレート樹脂またはポリアクリロニトリル樹脂 により形成されている請求項1に記載のロール状外用貼付剤。
- 3. 前記外用貼付剤が、支持体と、前記支持体の一面に積層された粘着層と、 前記粘着層に剥離可能に積層された被覆材とを備えるものであり、前記被覆材が、 ポリエチレンテレフタレート樹脂からなる離型フィルムである請求項1に記載の ロール状外用貼付剤。
 - 4. 前記外用貼付剤が、支持体と、前記支持体の一面に積層された粘着層とを備えるものであり、前記支持体が、伸縮性を有するポリエチレンテレフタレート樹脂またはポリブチレンテレフタレート樹脂からなる編布、織布又は不織布である請求項1に記載のロール状外用貼付剤。
 - 5. 前記外用貼付剤において、切り取り線が形成されている請求項1に記載のロール状外用貼付剤。
- 6. 前記切り取り線がミシン目の切れ目であり、前記切れ目の幅が1.0~2. 25 0mm、前記切れ目同士の間隔が1.0~1.5mmであり、前記切れ目におい て前記外用貼付剤を破断する際の破断強度が、前記外用貼付剤に被覆材が積層さ

れている場合には7.36~15.24kgf/48mm幅であり、前記外用貼付剤に被覆材が積層されていない場合には0.76~2.65kgf/48mm幅である請求項1に記載のロール状外用貼付剤。

VERIFICATION

The undersigned, of the below address, hereby certifies that he/she well knows both the English and Japanese languages, and that the attached is an accurate English translation of the PCT application filed on <u>August 10, 2000</u> under No. PCT/JP00/05367.

The undersigned declares further that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this	6th	day of _	February	, 2002.
Signature:	himle	rosh	<u>.</u>	

Name: Shiro TERASAKI

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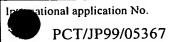
Translation



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

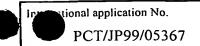
Applicant's or agent's file reference 2551WO0P	FOR FURTHER ACTION		ionofTransmittalofInternational Preliminary Report (Form PCT/IPEA/416)	
International application No.	International filing date (day		Priority date (day/month/year)	
PCT/JP99/05367	30 September 1999 ((30.09.99)	30 September 1998 (30.09.98)	
International Patent Classification (IPC) or national classification and IPC A61K 31/13, 31/445, 31/454, 31/4709, 31/55, 31/553, 31/4523, 31/4525, 31/4535, 31/473, 31/437, C07D 211/32, 401/06, 413/06, 405/06, 409/06, 471/06, 219/10, 221/18, 491/107, A61P 13/00				
Applicant TAK	KEDA CHEMICAL IND	OUSTRIES, L	TD.	
This international preliminary exami and is transmitted to the applicant ac		ed by this Interr	national Preliminary Examining Authority	
2. This REPORT consists of a total of	5 sheets, include	ding this cover s	heet.	
This report is also accompan been amended and are the bas Rule 70.16 and Section 607 o	sis for this report and/or sheet	s containing rec	iption, claims and/or drawings which have cifications made before this Authority (see CT).	
These annexes consist of a tot	tal of sheets			
3. This report contains indications relat	ting to the following items:			
Basis of the report				
II Priority	II Priority			
III Non-establishment o	of opinion with regard to nove	elty, inventive st	ep and industrial applicability	
IV Lack of unity of inve			,	
v Reasoned statement citations and explana	under Article 35(2) with rega ations supporting such statem	rd to novelty, in ent	ventive step or industrial applicability;	
VI Certain documents o	cited			
VII Certain defects in th	e international application			
VIII Certain observations	s on the international applicat	ion		
Date of submission of the demand	Date	of completion	of this report	
18 November 1999 (18.			July 2000 (24.07.2000)	
Name and mailing address of the IPEA/JP	Auth	norized officer	·	
Facsimile No.		phone No.		



I. Basis	of the report
1. With	regard to the elements of the international application:*
	the international application as originally filed
	the description:
	pages, as originally filed
	pages , filed with the demand
	pages, filed with the letter of
	the claims:
	as originally filed
	pages, as amended (together with any statement under Article 19
	pages, to discover (regently with the demand
	pages, filed with the letter of
	the drawings: pages , as originally filed
	filed with the demand
	pages, filed with the definant
_	pages, filed with the letter of
🔲 1	the sequence listing part of the description:
	pages, as originally filed
	pages, filed with the demand
	pages, filed with the letter of
the in	regard to the language, all the elements marked above were available or furnished to this Authority in the language in which international application was filed, unless otherwise indicated under this item. e elements were available or furnished to this Authority in the following language which is: the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With preli	n regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international minary examination was carried out on the basis of the sequence listing:
	contained in the international application in written form.
	filed together with the international application in computer readable form.
П	furnished subsequently to this Authority in written form.
	furnished subsequently to this Authority in computer readable form.
	The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
	The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4.	The amendments have resulted in the cancellation of:
	the description, pages
	the claims, Nos
	the drawings, sheets/fig
5.	This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**
in th	acement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to his report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 70.17).
	replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

III. Noi	III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
1. The indu	1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:				
	the entire international application.				
\boxtimes	claims Nos. 25				
beca	use:				
\boxtimes	the said international application, or the said claims Nos. 25 relate to the following subject matter which does not require an international preliminary examination (specify):				
	Relates to a method for treatment of the human body by therapy. (PCT Article 34(4)(a)(i) and Rule I(iv).)				
	•				
:	· · · · · · · · · · · · · · · · · · ·				
•					
	the description, claims or drawings (indicate particular elements below) or said claims Nosare so unclear that no meaningful opinion could be formed (specify):				
·.					
	the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed.				
	no international search report has been established for said claims Nos				
2. A n	neaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid uence listing to comply with the standard provided for in Annex C of the Administrative Instructions:				
	the written form has not been furnished or does not comply with the standard.				
	the computer readable form has not been furnished or does not comply with the standard.				

Claims



NO

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
1. Statement				
Novelty (N)	Claims	2-20,23	YES	
•	Claims	1,21,22,24	NO NO	
Inventive step (IS)	Claims		YES	
	Claims	1-24	NO	
Industrial applicability (IA)	Claims	1-24	YES	

2. Citations and explanations

Document 1: JP, 8-245582, A (Kyorin Pharmaceutical Co., Ltd.), 24 September, 1996 (24.09.96)

Document 2: JP, 8-245583, A (Kyorin Pharmaceutical Co., Ltd.), 24 September, 1996 (24.09.96)

Document 3: EP, 607864, A2 (Takeda Chemical Industries, Ltd.), 27 July, 1994 (27.07.94)

Document 4: EP, 296560, A1 (Eisai Co., Ltd.), 28 December, 1988 (28.12.88)

Document 5: EP, 500006, A1 (Hoechst-Roussel Pharmaceuticals Incorporated), 26 August, 1992 (26.08.92)

Document 6: US, 5177082, A (Chao-mei Yu), 5 January, 1993 (05.01.93)

Document 7: WO, 92/20327, A1 (Snorrason), 26 November, 1992 (26.11.92)

Document 8: JP, 9-20755, A (Hokuriku Seiyaku Co., Ltd.), 21 January, 1997 (21.01.97)

Claims 1, 21, 22, 24

Documents 1 and 2 disclose drugs for treating urinary disorders (such as anuresis and dysurea) that contain quaternary ammonium compounds that are cholinergic substances. Moreover, there is a high probability that said cholinergic substances have an acetylcholinesterase inhibitory effect. The subject matter of claims 1, 21, 22 and 24 is thus considered not to be novel.

Claims 2-16

Document 3 discloses the fact that the amine compounds disclosed in claims 2-16 have an acetylcholinesterase inhibitory effect, and so it is considered that it would have been easy for a person skilled in the art to conceive of trying out the compounds disclosed in document 3 in place of the cholinergic substances disclosed in documents 1 and 2. The subject matter of claims 2-16 is thus considered not to involve an inventive step.

Claim 17

Document 4 discloses the fact that the specific amine compounds disclosed in claim 17 have an acetylcholinesterase inhibitory effect, and so it is considered that it would have been easy for a person skilled in the art to conceive of trying out the compounds disclosed in document 4 in place of the cholinergic substances disclosed in documents 1 and 2. The subject matter of claim 17 is thus considered not to involve an inventive step.

Claim 18

Document 5 discloses the fact that the specific amine compounds disclosed in claim 18 are useful in the treatment of diseases whose characteristic feature is a reduction in cholinergic function, and so it is considered that it would have been easy for a person skilled in the art to conceive of trying out the compounds disclosed in document 5 in place of the cholinergic substances disclosed in documents 1 and 2. The subject matter of claim 18 is thus considered not to involve an inventive step.

ional application No. PCT/JP99/05367

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V (Citations and explanations):

Claim 19

Document 6 discloses the fact that the specific amine compounds disclosed in claim 19 have an acetylcholinesterase inhibitory effect, and so it is considered that it would have been easy for a person skilled in the art to conceive of trying out the compounds disclosed in document 6 in place of the cholinergic substances disclosed in documents 1 and 2. The subject matter of claim 19 is thus considered not to involve an inventive step.

Claim 20

Document 7 discloses the fact that the specific amine compounds disclosed in claim 20 have an acetylcholinesterase inhibitory effect, and so it is considered that it would have been easy for a person skilled in the art to conceive of trying out the compounds disclosed in document 7 in place of the cholinergic substances disclosed in documents 1 and 2. The subject matter of claim 20 is thus considered not to involve an inventive step.

Claim 23

and the 7

Document 8 discloses the fact that an α_{l} -receptor antagonist is useful as an agent for treating dysurea ([0007]), and so it is considered that it would have been easy for a person skilled in the art to conceive of trying combining the α_1 -receptor antagonist disclosed in document 8 with the agents for treating dysurea disclosed in documents 1 and 2. The subject matter of claim 23 is thus considered not to involve an inventive step.

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

HASEGAWA, Yoshiki Soei Patent and Law Firm, Okurahonkan

6-12. Ginza 2-chome Chuo-ku, Tokyo 104-0061 **JAPON**

IMPORTANT NOTIFICATION

International application No. PCT/JP00/05367

International filing date (day/month/year) 10 August 2000 (10.08.00)

International publication date (day/month/year)

06 November 2000 (06.11.00)

Priority date (day/month/year)

Not yet published

10 August 1999 (10.08.99)

FP00-0174-00

Date of mailing (day/month/year)

Applicant's or agent's file reference

Applicant

HISAMITSU PHARMACEUTICAL CO., INC. et al

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau. as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
10 Augu 1999 (10.08.99)	11/226657	JP	03 Octo 2000 (03.10.00)
27 Janu 2000 (27.01.00)	2000/19050	JP	03 Octo 2000 (03.10.00)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

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From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
HASEGAWA, Yoshiki
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JAPON

Date of mailing (day/month/year)
22 February 2001 (22.02.01)

Applicant's or agent's file reference

FP00-0174-00

IMPORTANT NOTICE

International application No. PCT/JP00/05367

International filing date (day/month/year) 10 August 2000 (10.08.00) Priority date (day/month/year)
10 August 1999 (10.08.99)

Applicant

HISAMITSU PHARMACEUTICAL CO., INC. et al

 Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice: KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

BR,CN,EP,ID,VN

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

 Enclosed with this Notice is a copy of the international application as published by the International Bureau on 22 February 2001 (22.02.01) under No. WO 01/12165

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

J. Zahra

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	SIFICATION OF SUBJECT MATTER C1 ⁷ A61K9/70, 45/00, A61P29/00				
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According to International Patent Classification (IPC) or to both national classification and IPC					
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Minimum documentation searched (classification system followed by classification symbols) Int.Cl ⁷ A61K9/70, 45/00, A61P29/00, B65H35/07					
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Jitsuyo Shinan Koho 1926-1992 Toroku Jitsuyo Shinan Koho 1994-1996 Kokai Jitsuyo Shinan Koho 1971-1992 Jitsuyo Shinan Toroku Koho 1996-1999					
Electronic d	ata base consulted during the international search (nam	e of data base and, where practicable, sea	rch terms used)		
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	MENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where ap		Relevant to claim No.		
Y	Microfilm of the specification the request of Japanese Util No.187062/1980 (Laid-open No.11 (Kyounosuke SUDA),	lity Model Application	1-10		
	10 July, 1982 (10.07.82), Full text; Figs. 1 to 5 (Fami	ly: none)	;		
Y	Microfilm of the specification the request of Japanese Util No.34256/1979 (Laid-open No.134 (NICHIBAN COMPANY, LIMITED), 25 September, 1980 (25.09.80), Full text; Fig. 1 (Family: no	lity Model Application	1-10 (
Y	Microfilm of the specification the request of Japanese Util No.135016/1979 (Laid-open No.60 (NICHIBAN COMPANY, LIMITED), 23 May, 1981 (23.05.81), Full text; Fig. 1 (Family: no	lity Model Application () 0730/1981)	1-10		
Further	documents are listed in the continuation of Box C.	See patent family annex.			
"A" docume consider c	considered to be of particular relevance earlier document but published on or after the international filing date L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) O" document referring to an oral disclosure, use, exhibition or other means understand the principle or theory underlying the invention cannot be considered novel or cannot be considered novel or cannot be considered novel or cannot be document is taken alone document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered novel or cannot b				
	ailing address of the ISA/ nese Patent Office	Authorized officer			
Facsimile No) .	Telephone No.			



Coteconit	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Category*	sign of the specification and drawings annexed to	1-10
. · Y	the request of Japanese Utility Model Application No.192794/1984 (Laid-open No.108257/1986)	•
	(NEC Corporation), 09 July, 1986 (09.07.86),	•
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